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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
UTSG:231US

I hereby certify that this correspondence is being electronically submitted to the Commissioner for Patents	Application Number	Filed
on December 22, 2006	09/587,653	June 5, 2000
Signature /Charles P. Landrum/	First Named Inventor: David V. Sangar	
Typed or printed name Charles P. Landrum	Art Unit: 1648	Examiner: Li, Bao Q.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant/inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 46,855
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

/Charles P. Landrum/
Signature

Charles P. Landrum
Typed or printed name

(512) 536-3167
Telephone number

December 22, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

- [ ] *Total of _____ forms are submitted.

Arguments in Support of Pre-Appeal Brief Request for 09/587,653

I. Claims 51-55 are Entitled to the Benefit of Priority to U.S. Provisional Patent Application Serial Number 60/137,665 (the '665 application) filed on June 4, 1999

In the final Office Action claims 51-55 are denied the benefit of priority to the '665 application filed on June 4, 1999, based on the lack of an enabling disclosure for SEQ ID NO:2 in the '655 application.

There is no need to provide an enabling disclosure of SEQ ID NO:2 because any portion of SEQ ID NO:2 that is not included in the novel SEQ ID NO:1 was already known. Applicant need not enable what was already known to one of ordinary skill in the art. Applicants note that the full sequence of SEQ ID NO:2 was not provided in the provisional application, because the incomplete 5' portion of the GBV-B sequence was already available to one of ordinary skill in the art at the time the '665 application was filed. The standard for enablement requires the description to enable one reasonably skilled in the art in making or using the invention from the disclosure *coupled with information known in the art* without undue experimentation.

Applicants plainly state on page 4 or the '655 application that they "have elucidated the previously unrecognized 3' terminal sequence of GBV-B (SEQ ID NO;1). This sequence has been reproducibly recovered from tamarin serum containing GBV-B RNA, in RT-PCR protocols using several different primer sets, and as a fusion with previously reported 5' GBV-B sequences." Furthermore, page 9, lines 6 through 8 of the specification reads:

> Nucleic acids according to the present invention may encode the 3' sequence of the GBV-B genome set forth in SEQ ID NO:1,[or] *the entire GBV-B genome*... (emphasis added).

GenBank accession number U22304 dated April 12, 1995 is disclosed on page 32 of the specification. This GenBank entry contains the incomplete GBV-B genomic sequence representative of the published incomplete 5' GBV-B sequence lacking the 3' GBV-B sequence. One of skill in the art had access to the nucleotide sequence disclosed in GenBank accession U22304 prior to June 4, 1999.

The standard for satisfying the enablement requirement under 35 U.S.C. §112 ". . . is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent *coupled with information known in the art* without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) (emphasis added). The case law does not require re-description of what was already known, namely the incomplete 5' portion of the GBV-B genome. *Capon v. Dudas*, 418 F.3d 1349, 1357 (Fed Cir 2005). Thus, the present application's claim of priority to the '665 application extends to the subject matter of claims 51-55 because there is no legal basis for requiring enablement for the incomplete 5' portion of the GBV-B virus because it was already known.

II. Objection and Rejection of Claim 29 are Readily Addressed by Claim Amendment

The objection to and rejection of claim 29 under 35 U.S.C. § 112, second paragraph can be readily addressed by claim amendment.

III. Claims 19-20, 30-33, and 51-56 are Enabled by the Current Specification

The final Office Action rejects claims 19-20, 30-33, and 51-56 under 35 U.S.C. § 112, first paragraph, for lacking an enabling disclosure. The Examiner argues that (1) a reasonable interpretation of claim 19 includes any virus in the art; (2) a virus cannot be produced by only a portion of the 3' non-coding region of any virus or a portion or piece of DNA alone; (3) it is

unpredictable as to which cell the claimed virus will replicate in; and (4) the specification does not teach which segment is required for viral replication.

In regard to these points, the Examiner is factually incorrect. The specification clearly teaches one of ordinary skill in the art how to produce a virus by introducing into a host cell a recombinant GBV-B or chimeric GBV-B viral genome. The final Office Action admits to such on page 4 of the final Office Action that reads: ". . . while being enabling for producing an infectious GBV-B virus or a chimeric GBV-B/HCV virus . . . ." Reference is made to claim 19, as an example, that claims:

> Claim 19. A method of producing a virus comprising:
> introducing *into a host cell a* ***recombinant GBV-B or chimeric GBV-B viral genome*** *comprising a 3' terminal sequence of GBV-B, wherein the 3' terminal sequence* ***comprises*** *50 contiguous nucleotides from SEQ ID NO:1*; and
> culturing said host cell under conditions permitting production of a virus from said genome.

(1) In regard to enablement for production of any virus, it can be seen from the plain language of the claims that they are directed to virus produced from "a recombinant GBV-B or chimeric GBV-B ***viral genome.***" The Examiner is mistakenly interpreting the preamble ("A method of producing a virus") to somehow broaden the claims beyond "a recombinant GBV-B or chimeric GBV-B viral genome." Applicants note that they do not understand how one of skill in the art can produce a virus other than a GBV-B or chimeric GBV-B virus from a recombinant GBV-B or chimeric GBV-B viral genome.

(2) In regard to enablement for a DNA fragment to produce a virus, it also can be seen from the plain language of the claims that they are directed to a GBV-B or chimeric GBV-B viral genome *comprising* a 3' terminal sequence of GBV-B virus that *comprises* 50 contiguous nucleotides of SEQ ID NO:1. Again the Examiner is misconstruing the claim by looking beyond

the plain language. The Examiner is arguing that a virus cannot be produced from a mere DNA fragment. Applicants are a loss to explain how a GBV-B or chimeric GBV-B viral genome can be construed as a DNA fragment. Particularly in light of the claims that read "culturing said host cell under conditions permitting ***production of a virus from said genome***." Applicants only guess is that the Examiner is failing to read to the claims as whole and is construing the well known term "comprising" in way not readily recognized by applicants.

(3) In regard to the unpredictability of a cell to produce the virus, the claim language is again being incorrectly construed by the Examiner. The claim as whole is not being considered. The claims are directed to culturing the host cell under conditions permitting production of a virus from the genome. Applicants to not understand how the claims can include all cells, particularly those that cannot be cultured under conditions permitting production of a virus from the genome. Once again the Examiner is misconstruing the plain language of the claims.

(4) In regard to enablement for a segment that is required for viral replication, yet again the claim language is being misconstrued by the Examiner. The claims are directed to a viral genome that provides for an infectious GBV-B or chimeric GBV-B virus. This genome is further characterized by ***comprising*** 50 contiguous nucleotides of SEQ ID NO:1. The 50 contiguous nucleotides are present in the context of the infectious GBV-B genome, not as fragment or a non-functional genome.

IV. Claims 51-53 are patentable over U.S. Patent No. 6,627,437 ('437 patent)

Claims 51-53 are rejected under 35 U.S.C. § 102(e) as being anticipated by the '437 patent. Priority to the June 4, 1999 filing date is being denied based on a lack of an enabling disclosure. As described above and incorporated by reference here the denial of benefit of priority is incorrect. Thus, the '437 patent is not prior art against claims 51-53.

V. Claims 51-53 are Patentable over Bukh *et al.* (1999)

Claims 51-53 are rejected under 35 U.S.C. § 102(a) as being anticipated by Bukh *et al.* (September 1999). Priority to the June 4, 1999 filing date is being denied based on a lack of an enabling disclosure. As described above and incorporated by reference here the denial of benefit of priority is incorrect. Thus, the Bukh *et al.* reference is not prior art against claims 51-53.